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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Richard O. Chen

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WILSON, SONSINI, GOODRICH & ROSATI
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EXAMINER

RIGGS II, LARRY D

ART UNIT

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1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/632,099	Applicant(s) CHEN ET AL.	
	Examiner LARRY D. RIGGS II	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-9, 13, 14 and 62-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 13, 14 and 62-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/19/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments filed 14 September 2009 are acknowledged and entered.

Status of Claims

Claims 6, 10-12 and 15-61 are cancelled. Claims 1-5, 7-9, 13, 14 and 62-78 are currently pending and under consideration.

Information Disclosure Statement

The information disclosure statement filed 19 June 2009 is acknowledged. A signed copy of the corresponding 1449 form has been included with this Office action.

Withdrawn Rejections/Objections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn based on the amendments filed 14 September 2009. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-9, 13, 14 and 62-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes et al. (Cell, 2000, 102, 109-126) in view of Meltzer (Current Opinion in Genetics & Development, 2001, 11, 258-263) and further in view of Cho et al. (US 6,741,986).

The instant claims provide a system for identifying a drug discovery target comprising a database capable of storing genomics information, wherein the computer system is configured to perform analysis of biological relationships among a database of genomics information stored as an ontology, query the database to identify disease-

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related pathways, and identify objects, and processes which act on the objects, wherein each of the objects or pathways is a drug discovery target.

Regarding claim 1, Hughes et al. teaches the monitoring of hundreds of cellular components with the construction of a database (compendium) of expression profiles from mutation and chemical treatment within *S. cerevisiae*, (abstract; page 124, left column, first full paragraph; figures 1-3; table 3). Hughes teaches that an expression profile allows a user to analyze the cellular transcriptional response to different steps within a pathway and enables a user to determine the affect of disease on the pathway, (page 109, right column, last paragraph; page 118, right column). Hughes identifies components of cellular pathways as a novel targets of the drug dycyclonine, (abstract, page 115, right column; page 123, left column).

Hughes et al. does not teach a computer system configured/programmed to perform the recited steps of claim 1 and Hughes et al's database is not genomics information stored as an ontology.

Meltzer analyzes microarray data that would lead to identification of genes in pathways with a gene ontology database that categorizes hierarchical schemes according to molecular function, biological process and cellular component (page 260, left column, second paragraph – right column, third paragraph).

Meltzer teaches a gene ontology database and a system, i.e. high-density array pattern interpreter, where search engines carry out computations with the output of expression databases (page 260, right column, second and third paragraphs).

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However, Hughes et al. and Meltzer do not teach a computer system configured/programmed to perform the recited steps of claim 1.

Cho et al. teaches extracting information from a plurality of sources and stored in an information store according to an ontology, (column 2, lines 28-49). Cho et al. teaches a computer system (client system) that requests information from a server computer system, which performs processing in response to the client request and provides the requested information to the client systems, (column 4, lines 3-25), which suggests that the computer system of Cho et al. can be modified to perform the recited steps of claim 1, i.e. performing analysis of relationships, querying a database and identifying objects of the database.

Regarding claim 2, Hughes shows the use of a 2-color cDNA hybridization assay to produce 300 expression profiles, (page 111, left column, last paragraph - right column, first paragraph; page 124, right column, second paragraph; Figure 1).

Regarding claims 3-5, Hughes shows the database was proprietary when produced but now is available to the public, (page 124, left column, second and third paragraphs).

Regarding claims 7 and 8, the specification defines slots and facets as to define and structure the taxonomic relationship between classes or groups of things that share similar properties, (see specification, page 9, paragraphs 40 and 41). Hughes shows clustering analysis wherein profiles and transcripts were selected from a data matrix, and experiments and responsive genes were grouped by agglomerative hierarchical clustering, where the similarity measurement is the error-weighted correlation coefficient

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(page 124, third paragraph). Hughes shows genes and experiments were re-ordered according to the resulting clustering similarity trees and the significance (p value) for gene regulation takes the gene measurement error and biological variation in control into account, (page 124, third paragraph; Table 3).

Regarding claim 9, Hughes shows that a compendium may be used to discover unanticipated activities of drugs and ensure that only desired treatment effects are occurring in patients, (page 124, left column, first full paragraph).

Regarding claim 13, Hughes shows expression profiles of genes of both mutant and controls of *S. cerevisiae*.

Regarding claim 14, Hughes shows multiple steps of the same pathway from the 300 expression profiles and relational database, (abstract, page 109, right column; Table 3).

Regarding claim 62, Cho et al. teaches a plurality of databases and knowledge base of scientific findings, (column 5, lines 58-66; column 7, 51-58; column 15, lines 1-14).

Regarding claim 63, Cho et al. teaches a frame-based knowledge base, (column 14, line 66 – column 15, line 3).

Regarding claim 64, Hughes teaches comparing the expression profile of a pathway to a comprehensive database of reference profiles, (page 109, right column, last paragraph).

Regarding claim 65, Hughes teaches differential gene expression profiles, (page 112; Figures 1 and 2; Table 1).

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Regarding claims 66 and 71, Hughes teaches using the bootstrap method to obtain P values (significance) of each branch point in the comparison of experiment cluster tree, (page 113, left column - right column, second paragraph; Figures 1 and 2).

Regarding claim 67, Hughes teaches deviation from control experiments and profiles resulting from significant up and down regulation of genes, (page 112, right column, penultimate paragraph; Figure 2; Table 1).

Regarding claim 68, Cho et al. teaches information store is a knowledge base configured to store information according to an ontology, (column 5, lines 17-30).

Regarding claim 69, Hughes teaches an experiment cluster tree of genomic clusters that allows comparisons from experimental and control data, (page 113; Figure 1; Table 3).

Regarding claim 70, Hughes teaches a database of reference profiles used in comparison with an experimental profile, (abstract; page 109, right column, last paragraph; page 118, right column, second paragraph).

Regarding claims 72 and 73, Hughes teaches clusters resulting from both experimental and reference profiles from expression levels of microarray experiments, (pages 111 - 112; Figures 1 and 2).

Regarding claims 74 and 75, Meltzer teaches identifying genes with respect to known genes, (page 259, right column).

Regarding claim 76, Hughes teaches non-overlapping clusters with a threshold of statistical significance determined by the bootstrap method yielding P values of each of the branch points in the experiment cluster tree, (page 113).

Regarding claim 77, Hughes teaches the characterization of open reading frames by comparing expression profile of deletion mutant profiles to known mutant profiles and determining a drug target based on established targets of antifungal and antimicrobial compounds, (page 113, right column, last paragraph).

Regarding claim 78, Cho et al. teaches a network of computers and a communication network, (column 4, lines 18-58).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the functional discovery process via a compendium of expression profiles of Hughes et al. with use of the ontological relations by Meltzer and the computer system for information extraction and storage of a knowledge base by Cho et al. One skilled in the art would have been motivated to combine the ontological relations of Meltzer with the databases of Hughes et al. because Meltzer teaches that only by thoroughly combining the literature, can the most comprehensive picture of gene function be obtained, (page 260, right column, second paragraph). Cho et al. teaches automatically extracting information from a plurality of sources, analyzing the information and storing the information according to an ontology, (column 2, lines 28-49; column 8, line 64 – column 9, line 7) thus one of ordinary skill in the art would have been motivated to make the method of Hughes et al., Meltzer and Cho et al. completely automatic by comprising a system with instructions for executing all steps of the method to take the obvious advantage of a fully automatic process, i.e. saving time and cost.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LDR/

Larry Riggs

Examiner, Art Unit 1631

/Marjorie Moran/

Supervisory Patent Examiner, Art Unit 1631